Critique
"Arrival of Unapproved Select Agent Biotoxin at the NSLS"
Prepared by R. Casey
1/30/02

Present at Meeting - Andrew Ackerman (NSLS), Michael Becker (Biology), Lonny Berman (NSLS), Bob Casey (NSLS), Nick Gmur (NSLS), Frederick Horn (SHSD), Steve Moss (SHSD), Lawrence Stern (MIT), Bob Sweet (Biology)

Background - The purpose of the meeting was to review the recent event involving the unapproved arrival of a toxin listed by the Center for Disease Control (CDC) as a "Select Agent". Use of a select agent potentially requires special planning at the facility and specific approvals in advance from the CDC and DOE. It was determined during the authorization process at the beam line that this experiment not been approved by NSLS safety personnel. The experiment was not allowed to proceed while investigations were conducted of potential concerns. The material in question was ~ 10 nG Staphyloccal enterotoxin B crystals.

Following review with personnel from the Safety & Health Services Division and Laboratory legal staff, it was determined that this material was exempt from CDC registration for this application and that it could be used without prior approval of CDC or DOE. Department of Energy personnel were subsequently advised of the issue and our determination. In discussions with the Orps categorizer and the Deputy Director for Operations, it was determined that this was not a reportable occurrence.

However, it was clear that a breakdown in the safety review and communication process had occurred and that a critique of the events was warranted.

Description of events - The experimenter was a first time user at the NSLS and had initiated planning and scheduling in early January with the Principal Research Team (PRT) operating the beam line . He filed the required Safety Approval Form on 1/22/02. Because of his unfamiliarity with the process, he assumed that the experiment had been approved, and he and his team arrived at the NSLS on 1/29/02. The group received the required training and beam line orientation and then sought beam line authorization from the NSLS operations staff to begin their experiment. When it was realized that the experiment had not been approved, the Experimental Review Coordinator (ERC) was contacted. The ERC advised operations and beam line staff that the use of the this bio-toxin could not be approved and that its presence within the facility was a potential violation of federal regulations for these materials. NSLS ESH personnel took custody of the materials and placed and placarded the crystals and their container in a hazardous material storage area.

A meeting was immediately conducted with the Chair of the Institutional Biosafety Committee, the NSLS ERC, and personnel from the Safety and Health Services Division to determine specific regulatory requirements for this material. The Safety and Health

Services Division Manager subsequently discussed the issue with the Deputy Director of Laboratory Operations and a member of the Laboratory Counsel staff. During this discussion, it was determined that the material, while listed as a CDC select agent, was exempt from CDC requirements for this biomedical research application because its LD_{50} concentration in vertebrates was higher (therefore less dangerous) than a threshold specified in the regulation.

Following this determination, the user was permitted to begin work with other non-toxic protein crystals that had also been brought to the NSLS. Authorization to use the toxic crystals was provided on Wednesday afternoon 1/30 following this critique and other safety reviews.

Discussion

- The experimenter had properly identified the material in the initial planning with the PRT and in his submission of the SAF. The planned use of the toxin had not been noted by the PRT in their preparation and the SAF had not been reviewed by the ERC prior to the arrival of the users. Although the SAF notes that additional planning and discussion is needed for certain biological hazards, the user reported that he did not notice the requirement to contact the ERC at the time that he submitted the SAF. As a first time user without prior experience at the NSLS, he assumed that the experiment was approved since no one contacted him following submission of the SAF. It is important for the user to initiate contact for these types of special risk experiments and to ensure that the experiment has been approved before coming to the facility.

- The review of SAFs by the ERC is normally conducted within a few days of submission by the user. In this case, additional assignments resulting from a recent retirement and a change in work location had resulted in a back-log of unreviewed SAFs. The SAF for this experiment was a part of that back-log, and as a result had not been reviewed prior to the arrival of the experimenter.

- The SAF process and form has served the NSLS well and remains an effective tool for safety review. However, inexperienced users often report difficulty in navigating through the web-based form and it is easy to understand how requirements contained within the form could be overlooked.

- The actions on the part of the Operations Staff responding to the request for beam authorization was diligent and commendable. Their prompt identification that the review had not been completed was instrumental in insuring that this issue was addressed in a timely and appropriate manner.

- At the time of the critique, the evaluation of CDC registration and work place handling requirements for this toxin at the user's home institution were not clear. In subsequent discussion with ESH personnel from the institution, it was determined that considerable work had been conducted with regard to this toxin and the potential need

for CDC registration. Bio-safety personnel from the institution had consulted with CDC in 1997 and had a letter stating that the toxin was exempt from registration.

Causes

1. Much information is included in the PRT beamline material and the SAF form, thereby diluting the importance of certain information that may be critical to the safety review. The amount of information contributed to the PRT staff not identifying the material and the user not recognizing that he had an obligation to contact NSLS ESH personnel to complete the review.

2. The lack of contact by the user with the ERC and the backlog of unreviewed SAFs resulted in the ERC's lack of awareness of the planned use of toxins at X-25. The ERC was fully cognizant of the special requirements for this material and would have required the proper preparation for the material prior to arrival.

Recommendations

1. Strong re-emphasis should be placed within the NSLS user community of the importance of discussing "special risk" experiments with the PRT and ERC well in advance of the start date and, in particular, of the responsibility to confirm approval for these experiments prior to arrival.

2. Modifications should be made to the information forms provided by the user to the PRT and in the SAF to ensure that materials or equipment that are a "show-stopper" for the experiment are clearly highlighted. In the short-term, this emphasis should be through formatting improvements. In the longer term, the SAF should be modified so that special risk items are flagged electronically, and automatic warnings (e.g. emails) are sent to the user, the PRT and the ERC. It is important to raise these type of issues beyond the typical noise level associated with the busy schedules of the user, PRT, and ERC.

3. Information related to this incident should be circulated among synchrotron light source users and staff at the NSLS and elsewhere in the world. The current emphasis on the study of toxins and etiologic agents as a part of the response to terrorist threats will undoubtedly increase the frequency of research with these materials at light source facilities. There is an important need to ensure an awareness of the regulatory drivers that are associated with these materials. Failure to adhere to these requirements could have severe impact on a Light Source, including large fines (up to $500,000) and shut-down of a beam line or facility.